



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2015-0018, EPA-HQ-OPP-2015-0020; FRL-9945-76]**

**Quaternary Ammonium Compounds, Benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium Salts with Sepiolite; and Quaternary Ammonium Compounds, Benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium Salts with Saponite; Exemptions from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite (CAS Reg. No. 1574487-61-8) when used as an inert ingredient (suspending or structuring agent) in pesticide formulations applied to growing crops at a concentration not to exceed 2.0% by weight in the formulation, asbestos free and containing less than 1% crystalline silica. This regulation also establishes an exemption from the requirement of a tolerance for residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with

saponite (CAS Reg. No. 1588523-05-0) when used as an inert ingredient (suspending or structuring agent) in pesticide formulations applied to growing crops at a concentration not to exceed 1.0% by weight in the formulation. Technology Sciences Group on behalf of BYK Additives Inc. submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite.

**DATES:** This regulation is effective [*insert date of publication in the **Federal Register***].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the **Federal Register***], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

**SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** The dockets for these actions, identified by docket identification (ID) number EPA-HQ-OPP-2015-0018, EPA-HQ-OPP-2015-0020 are available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket

is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0018 (CAS Reg. No. 1574487-61-8), EPA-HQ-OPP-2015-0020 (CAS Reg. No. 1588523-05-0) in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request,

identified by docket ID number EPA-HQ-OPP-2015-0018, EPA-HQ-OPP-2015-0020 by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of April 6, 2015 (80 FR 18327) (FRL-9924-00), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of pesticide petitions (PP IN-10780) and (PP IN-10781) by Technology Sciences Group on behalf of BYK Additives Inc., 1600 West Hill Street Louisville, KY 40210. The petitions requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite (CAS Reg. No. 1574487-61-8) when used

as an inert ingredient suspending or structuring agent in pesticide formulations applied to growing crops with a limitation of 2.0% in formulation, asbestos free and containing less than 1% crystalline silica; and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite (CAS Reg. No. 1588523-05-0) when used as an inert ingredient suspending or structuring agent in pesticide formulations applied to growing crops with a limitation of 1.0% in formulation.

That document referenced a summary of the petitions prepared by Technology Science Group, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notices of filing.

### **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate

exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite, and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.



Specific information on the studies received and the nature of the adverse effects caused by both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Based on data in structurally similar quaternary ammonium clay substances, quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite have low acute toxicity via the oral, dermal and inhalation routes in rats. The substances are expected to be a slight skin and eye irritant. A structurally similar quaternary ammonium clay substance did not cause skin sensitization in guinea pigs.

Multiple 28-day repeat-dose studies consistently showed high No Observed Adverse Effect Levels (NOAELs), typically the highest dose tested, which was 1,000 milligrams/kilogram/day (mg/kg/day) in rats. There was an absence of test substance-related toxicologically significant effects at any of the doses administered, including for neurological and immunological endpoints. Similarly, there were no effects on reproductive or developmental endpoints and no evidence for genotoxicity in multiple *in vitro* and *in vivo* assays (OECD 471, 474 and 476 on multiple quaternary ammonium compounds).

Clays treated with quaternary ammonium compounds have low water solubility, a high hydrophobic partition coefficient and relatively high molecular weight. All three

factors indicate likely limited absorption following ingestion, dermal exposure or inhalation. Based on similarities to other quaternary ammonium clays (high molecular weights, low water solubility, high hydrophobicity), both benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite would also be almost completely eliminated from the body shortly after oral dosing. Therefore, the biological availability is expected to be low.

#### *B. Toxicological Points of Departure/Levels of Concern*

1. The available toxicity studies indicate that both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite have very low overall toxicity. The NOAELs were  $\geq 1,000$  mg/kg/day (limit dose). Since signs of toxicity were not observed at the limit dose an endpoint of concern for risk assessment purposes were not identified. Therefore, since no endpoint of concern was identified for the acute and chronic dietary exposure assessment and short and intermediate dermal and inhalation exposure, quantitative risk assessments for both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite are not necessary.

#### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite, EPA considered exposure under the proposed exemption from the requirement of a

tolerance. EPA assessed dietary exposures from both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite in food as follows:

Under this exemption from the requirement of a tolerance, residues of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite may be found on foods from crops that were treated with pesticide formulations containing both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite. However, quantitative dietary exposure assessments were not conducted since endpoints for risk assessment were not identified.

2. *Dietary exposure from drinking water.* Since hazard endpoints of concern were not identified for the acute and chronic dietary assessments, quantitative dietary exposure risk assessments for drinking water were not conducted, although exposures may be expected from use on food crops.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite may be used in pesticide products and non-pesticide products that may be used around the home. Based on the discussion in Unit IV.B., quantitative residential exposure

assessments for both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found either quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite or with saponite to share a common mechanism of toxicity with any other substances, and both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on the lack of toxicity of ammonium acetate in the available studies and its chemical properties, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

*E. Aggregate Risks and Determination of Safety*

Taking into consideration all available information both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite when used as an inert ingredient (suspending or structuring agent) with a limitation of 2.0% in formulation, asbestos free and containing less than 1% crystalline silica and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite when used as an inert ingredient (suspending or structuring agent) with a limitation of 1.0% in formulation, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite when used as an inert ingredient in pesticide formulations applied to growing crops with a limitation of 2.0% in formulation,

asbestos free and containing less than 1% crystalline silica and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite when used as an inert ingredient (suspending or structuring agent) with a limitation of 1.0% in formulation, is safe under FFDCA section 408.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite are not expected to pose an acute risk.

2. *Chronic risk.* A chronic aggregate risk assessment takes into account subchronic and chronic exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a subchronic or chronic oral exposure were identified and no chronic dietary endpoints were selected. Therefore, quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite is not expected to pose a chronic risk.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, both

quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite were not expected to pose short-term risks.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, both quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite and with saponite were not expected to pose intermediate-term risks.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit IV.A., EPA does not expect either quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite or with saponite to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to either quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite or with saponite residues.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

Although EPA is establishing a limitation on the amount of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite; and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption from the requirement of tolerance. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. EPA will not register any pesticide for sale or distribution for use on growing crops with concentrations of quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite exceeding 2.0% by weight of the formulation, asbestos free and containing less than 1% crystalline silica; and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite exceeding 1.0% by weight of the formulation.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is



recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite, and quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite.

## **VI. Conclusions**

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180. 920 for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite (CAS Reg. No. 1574487-61-8) when used as an inert ingredient (suspending or structuring agent) in pesticide formulations applied to growing crops with a limitation of 2.0% in formulation, asbestos free and containing less than 1% crystalline silica; and for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite (CAS Reg. No. 1588523-05-0) when used as an inert ingredient (suspending or structuring agent) in pesticide formulations applied to growing crops with a limitation of 1.0% in formulation.

## **VII. Statutory and Executive Order Reviews**

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the

distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 10, 2016.

G. Jeffery Herndon,

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.920, add alphabetically the inert ingredients “Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite” and “Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite” to the table to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

| Inert ingredients   | Limits   | Uses                            |
|---|--|---------------------------------|
| * * *   | **   | **                              |
| Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with saponite (CAS Reg. No. 1588523-05-0) | Not to exceed 1.0% by weight of pesticide formulation  | Suspending or structuring agent |
| Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts   | Not to exceed 2.0% by weight of pesticide formulation, | Suspending or structuring agent |

|  |  |    |
|--|--|----|
| with sepiolite (CAS Reg. No. 1574487-61-8) | asbestos free and containing less than 1% crystalline silica |    |
| * * *                                      | **   | ** |

[FR Doc. 2016-11743 Filed: 5/17/2016 8:45 am; Publication Date: 5/18/2016]